

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application. No. : 10/766,684
First Named Inventor : Nabil L. Muhanna
Filing Date : January 28, 2004
Title : ARTIFICIAL INTERVERTEBRAL DISC
Group Art Unit : 3738
Examiner : Bruce Edward Snow
Confirmation No. : 2069

DECLARATION UNDER 37 C.F.R. § 1.131

We, Nabil L. Muhanna and Lance M. Middleton, hereby declare the following:

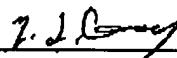
1. We are the named co-inventors in the above-identified U.S. Application No. 10/766,684 filed January 28, 2004.
2. We conceived and reduced to practice the invention disclosed and claimed in the above-identified application for patent in the United States of America prior to April 12, 2002, the earliest effective date of the cited references, U.S. Application Publication No. 2004/0176850 (to Zubok, et al.) and U.S. Application Publication No. 2005/0267582 (to Feree, et al).
3. The subject matter claimed and disclosed in the above-identified application was reduced to practice by us before April 12, 2002, as evidenced by photographs attached hereto as **Exhibits A-E.**

4. Provided in **Exhibits A-E** are actual photographs taken by Lance Middleton illustrating various views of a representative prototype of an artificial intervertebral disc fabricated under the direction of Lance Middleton prior to April 12, 2002, and, within the scope of Claims 19, 21-23, 25, 28-32, 35 and 42, having a first surface (see overlay marking 10) that is a concave-convex articulating surface and a second surface (see overlay marking 20) as a base adapted for fixation to a first bone surface, wherein the concave-convex surface has a hyperbolic paraboloid shape, as shown by the overlaid dashed lines. The overlay markings have been added for clarity and to identify aspects of the invention, particularly within the scope of the claims.
5. Provided in **Exhibit F** are representative engineering drawings in five views marked as F-1 to F-5 recently prepared by Lance Middleton showing dimensions of the prototype as depicted in Exhibits A-E, dimensions that were use to fabricate the prototype depicted in Exhibits A-E under the direction of Lance Middleton prior to April 12, 2002. Exhibit F shows, within the scope of Claims 19, 21-23, 25, 28-32, 35 and 42, engineered drawings of the prototype of an artificial intervertebral disc having a first surface marked as 10 that is a concave-convex articulating surface (see F-1, F-2, F-4 and F-5) and a second surface marked as 20 that is a base adapted for fixation to a first bone surface (see F-2, F-3, F-4 and F-5), wherein the concave-convex articulating surface has a hyperbolic paraboloid shape (see F-2, F-4 and F-5) as evidenced by a concave radius R1, which is 1.500 inches (see F-2 and F-4), and by a convex radius R2, which is 0.750 inches (see F-2, F-3, F-4 and F-5).

6. Provided in **Exhibit G** is a copy of an engineering drawing prepared originally by Lance Middleton prior to April 12, 2002, and similar to FIG. 6 in the as-filed specification, showing, within the scope of Claims 19, 21-23, 25, 28-36 and 42, an artificial intervertebral disc body (see overlay marking 5) having a first surface (see overlay marking 10) that is a concave-convex articulating surface with a hyperbolic paraboloid shape and a second surface (see overlay marking 20) as a base adapted for fixation to a first bone surface, such that when positioned between two cervical spine vertebra the artificial intervertebral disc body facilitates the natural kinetic motion of the cervical vertebrae, which is illustrated as an instantaneous axis of rotation (IAR) of the superior vertebrae (see overlay marking 40) with respect to the inferior vertebra (see overlay marking 50), wherein B1 and A1 depict two neutral locator positions of the superior vertebra and B2 and A2 show two flexed locator positions of the superior vertebra after a movement in flexion. The overlay markings have been added for clarity and to identify aspects of the invention, particularly within the scope of the claims.
7. **Exhibits A-G** are evidence of a successful test sample and actual reduction to practice prior to April 12, 2002, of an artificial intervertebral disc within the scope of Claims 19, 21-23, 25, 28-36 and 42 of the above-identified application for patent.
8. Pursuant to the evidence set forth in **Exhibits A-G**, the artificial intervertebral disc as described and claimed in U.S. Application No. 10/766,684 was reduced to practice in the United States prior to April 12, 2002.

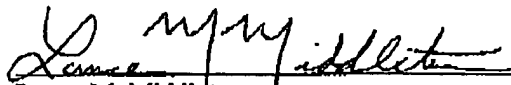
9. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed on the 14th day of April, 2008, in Gainesville, Georgia.



Nabil L. Muhanna

Executed on the 10 day of April, 2008, in Soddy Daisy, Tennessee.



Lance M. Middleton

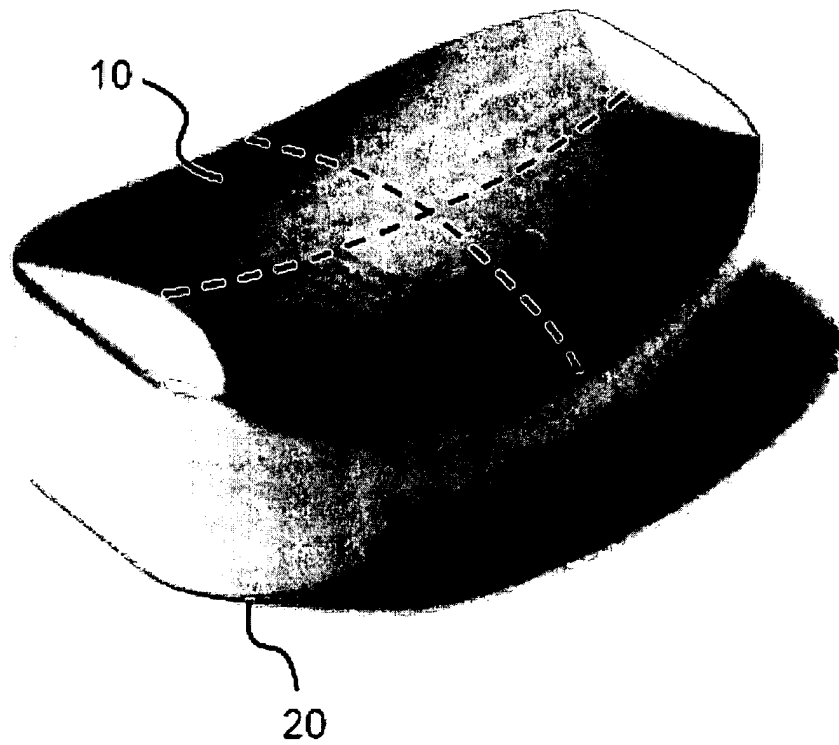


EXHIBIT A

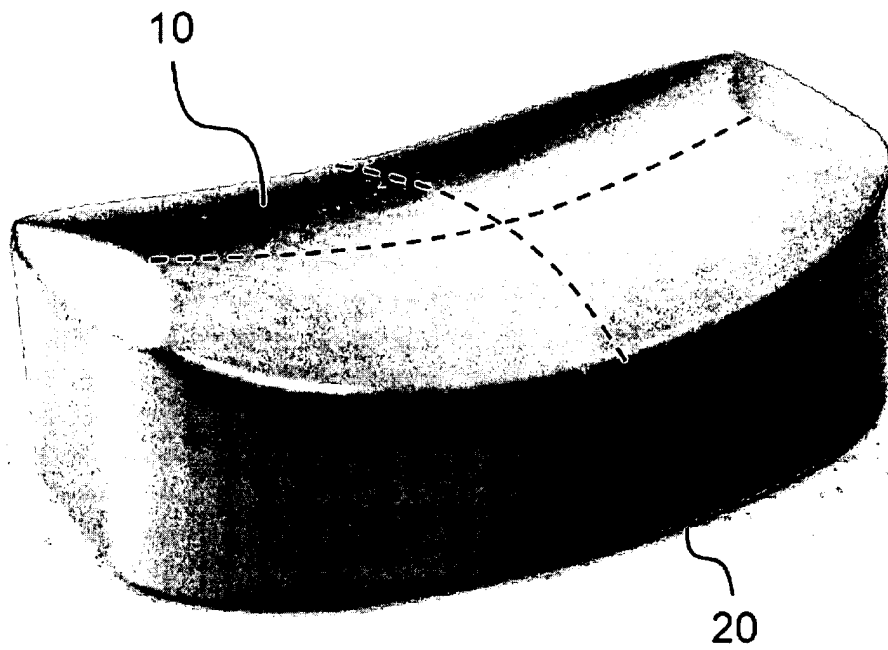


EXHIBIT B

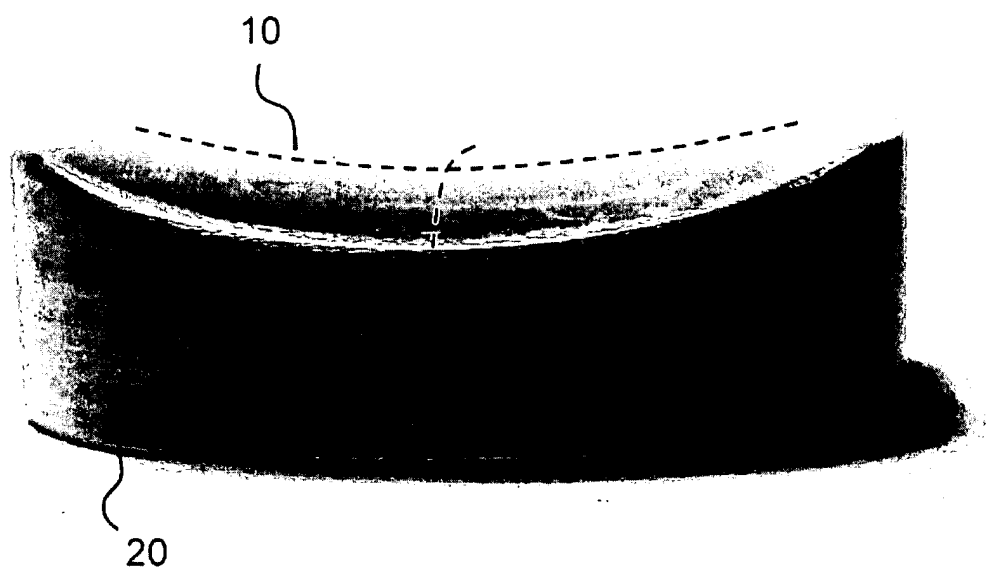


EXHIBIT C

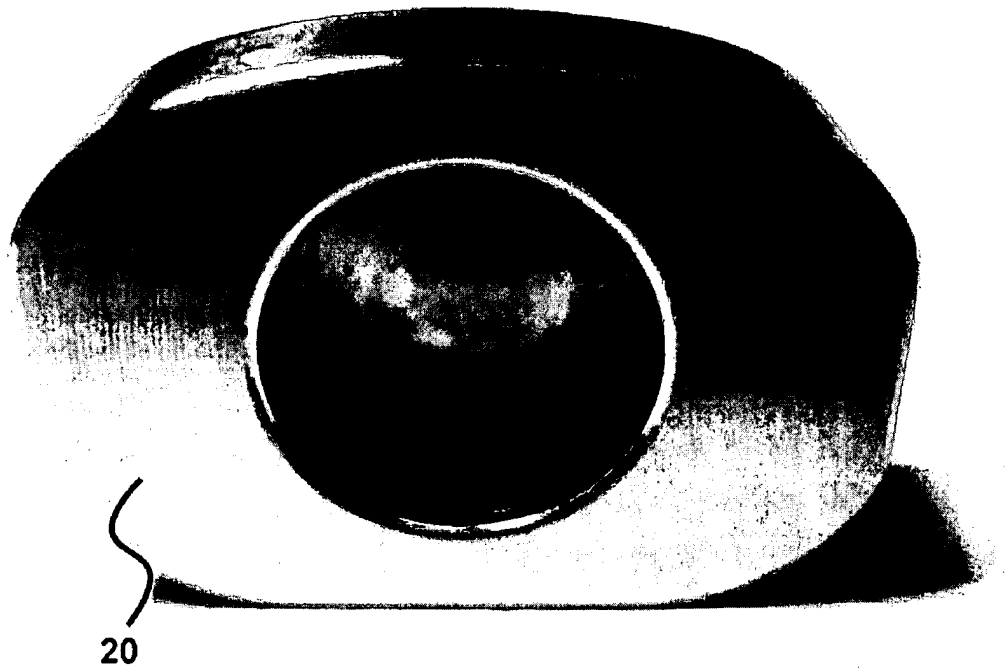


EXHIBIT D

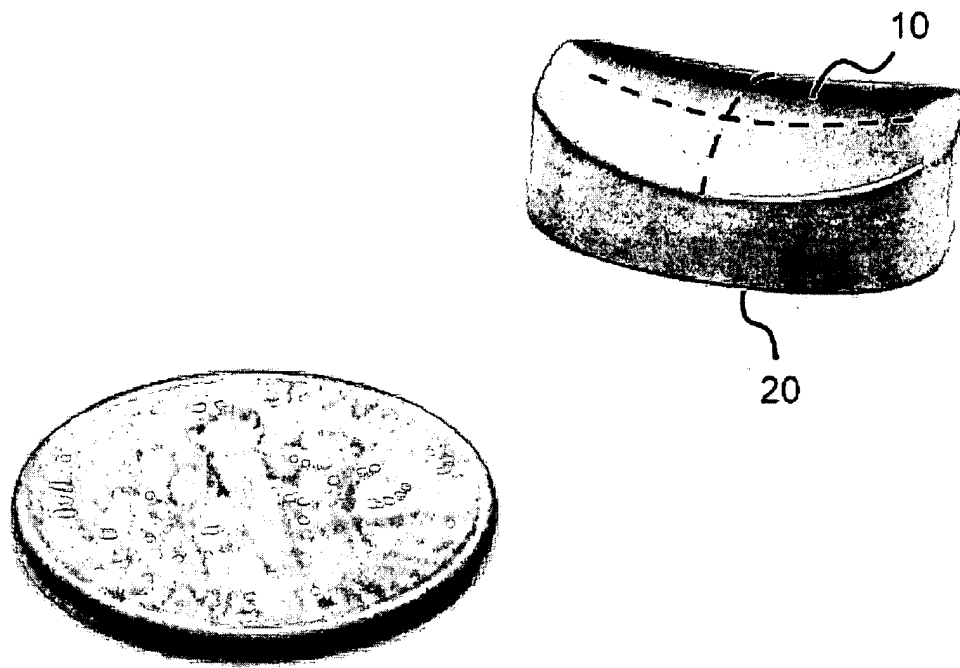
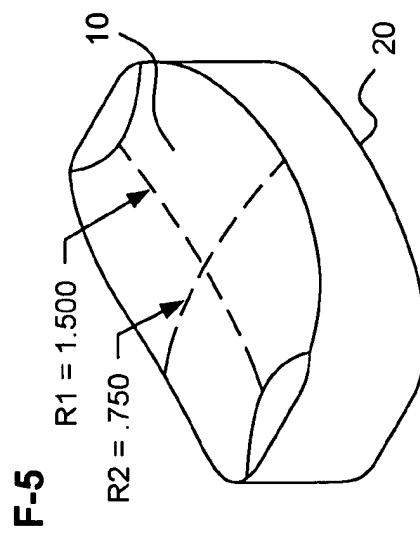
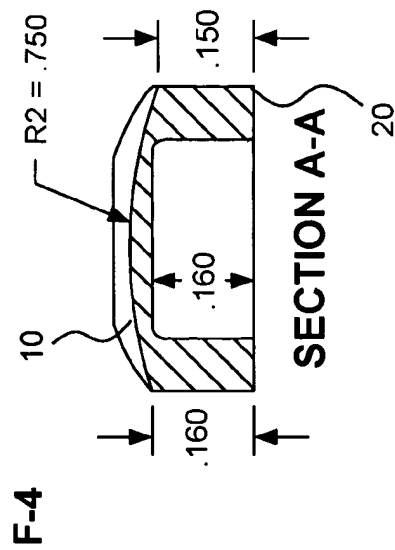
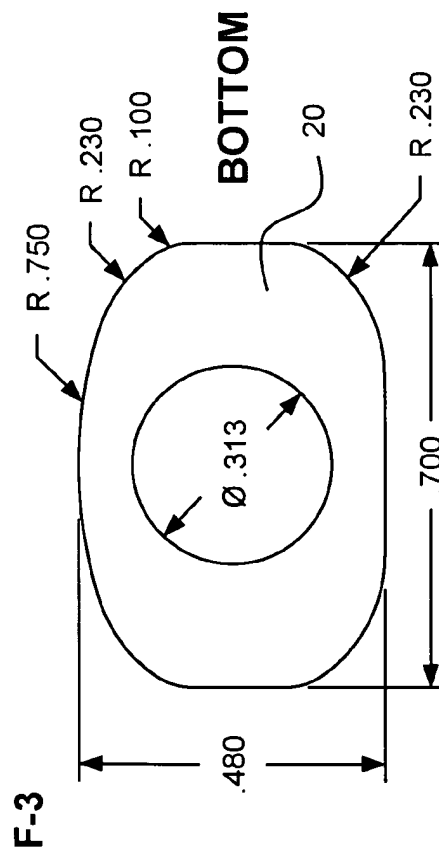
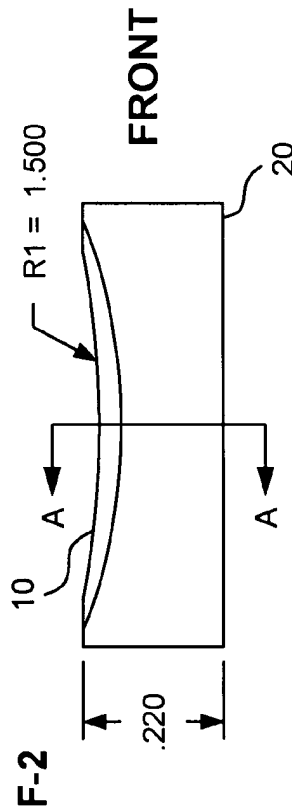
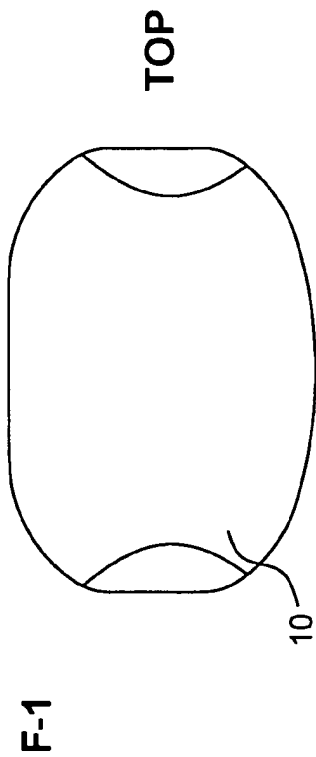


EXHIBIT E



(all dimensions are inches)

EXHIBIT F

